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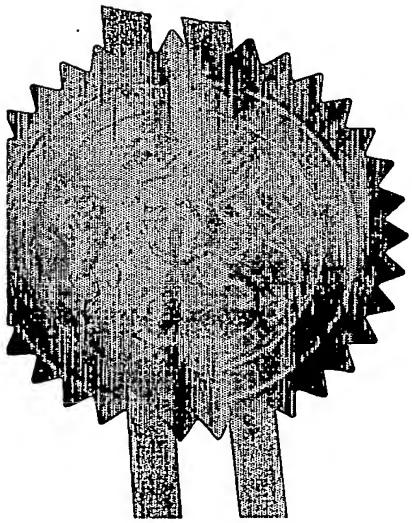

Signed Andrew Gersey

Dated 18 September 2003

Patents Form 1/77

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Request for grant of a patent

(see the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
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South Wales NP10 8QQ

1. Your reference — SJB/P11755

2. Patent application number *(The Patent Office will fill in this part)* — 0219342.3 — 20 AUG 2002

3. Full name, address and postcode of the applicant *(underline all surnames)*

DePuy International Ltd.
St. Anthony's Road
Leeds
LS11 8DT

Patents ADP number *(if you know it)*

If the applicant is a corporate body, give the country/state of its incorporation — GB — 6004733002

4. Title of the invention — A GUIDE BLOCK FOR USE IN SURGERY

5. Name of your agent *(if you have one)* — **URQUHART-DYKES & LORD**

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Tower House
Merrion Way
Leeds LS2 8PA
United Kingdom

Patents ADP number *(if you know it)* — **1644004**

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day/month/year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day/month/year)*

8. Is a statement of Inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*
a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

Yes

A GUIDE BLOCK FOR USE IN SURGERY

This invention relates to a guide block which can be used in surgery, especially orthopaedic surgery, to locate a surgical tool accurately.

Surgical instruments are commonly used to locate a tool accurately during the course of a surgical procedure. In orthopaedic procedures which involve implanting a joint prosthesis, this can be important to ensure correct alignment of the prosthesis. For example, it is generally required to resect a patient's natural bone in a procedure to implant a prosthesis, and reliable performance of the prosthesis requires that the bone is resected accurately.

Accurate location of a tool can be achieved by means of a guide block. This can include one or more structural features which can be engaged by the tool. The guide block is fastened to the patient's bone, so that the tool can be positioned against the structural features which can provide a point of reference for locating the tool. For example, when the tool is a saw, the structural feature can be a surface, or a pair of surfaces which define a slot, against which the saw blade is moved. When the tool is a drill, the structural feature can comprise an opening in which a drill bit can be inserted.

In order for the guide block to be able to provide accurate location of a tool, it is vitally important for the structural feature(s) of the guide block to be located accurately relative to the patient's anatomical features. The desired location of the structural feature(s) can be determined during pre-operative planning with reference to images of the patient's anatomy. It can also be determined intra-operatively based on exposed bones. Fixing of a guide block to a patient's bone is commonly achieved using bone screws or pins or both, which can be inserted into pre-drilled holes. However, especially in the absence of a stabilising device such as an ankle clamp, it can be difficult to determine the appropriate positions for the bone screws and inaccurate positioning of the bone screws leads to inaccurate positioning of the guide block and therefore also of the relevant structural features.

The present invention provides a guide block which comprises a fixation part and a guide part, which can be moved relative to the fixation part by means of a drive unit.

Accordingly, in one aspect, the invention provides a guide block for use in surgery to locate a surgical tool accurately relative to an anatomical feature, which comprises a fixation part which can be fastened directly to the patient's tissue, and a guide part having at least one structural feature to engage a surgical tool to ensure that the tool is located appropriately relative to the patient's tissue, the guide part being mounted on the fixation part, the instrument including at least one indexed drive by which the position of the fixation part relative to the guide part can be adjusted.

The guide block of the invention has the advantage that it provides for locating the structural feature engaged by the surgical tool separately from fixing the guide block to the patient's tissue. The fixation part of the guide block can be fixed to the patient's tissue in a first step, and any inaccuracy in its location can be corrected by subsequent movement of the guide part relative to the fixation part using the drive. This has the advantage of greatly simplifying the fixation of a guide block to a patient's bone or other tissue. It can also provide for significantly greater accuracy in the location of the structural feature of the guide block relative to landmarks on the patient's anatomy.

In the guide block of the invention, the structural feature can comprise a guide surface which can be engaged by a cutting tool such as a blade to define the appropriate alignment for a cut. When the guide surface is planar, it will define a cutting plane. However, it can be curved or otherwise non-planar, so that the patient's tissue is cut along a curved line. It might also have two parts which define separate cut lines, which might but need not intersect. The structural feature can comprise a pair of closely spaced guide surfaces which define between them a slot in which a blade can be inserted.

The structural feature can comprise an opening in which a drill bit can be inserted. The guide part of the block can provide more than one opening for a drill bit, for example two or three openings. The guide block of the invention can be used in this way to locate

accurately a position for an implant, or for another surgical tool which is to be fastened to a patient's bone or other tissue, for example by means of screws.

The fixation part of the guide block can be fastened to the patient's bone or other tissue by means of at least one fastener, generally two or three fasteners. Suitable fasteners might include, for example, pins or screws. It can therefore be preferred for the fixation part to have at least one opening, preferably a plurality of openings, extending through it in which one or more fasteners can be located for fixing the part to the patient's tissue.

Preferably, the drive includes at least one threaded shaft on one of the fixation part and the guide part, and a threaded bore in the other of the fixation part and the guide part. The threaded shaft can be received in the threaded bore so that the position of the guide part relative to the fixation part can be adjusted by rotating the shaft relative to the bore. Generally, it will be preferred for the shaft to be fastened to one of the fixation part and the guide part in a way which allows it to be rotated relative to that part, and for the threaded bore to be fixed. The shaft can be fixed by means of cooperating rib and groove. For example, the shaft can have a groove extending around its circumference, in which a rib on the fixation part or the guide part protrudes. The groove can be provided by two parts of the shaft which, when assembled together, provide opposite surfaces which can engage the rib between them. One part of the shaft can be a screw which is received in a bore in the other part of the shaft.

The drive can operate pneumatically, for example using a fluid delivery line and a reservoir, in which the amount of fluid or the pressure of the fluid can be adjusted to change the relative positions of the fixation and guide parts.

The drive can include a knob which can be engaged manually to cause relative rotation between the shaft and the bore.

The guide block can include a flexible drive shaft which can be connected to the guide part, through which rotational motion can be imparted to the guide part from a remote location to cause relative rotation between the shaft and the bore. For example, rotational motion

can be provided by an external motor. Rotational motion might also be provided manually and transmitted to the guide block by means of the drive shaft.

It will generally be preferred for the guide block to include at least two drives for adjusting the position of the guide part relative to the fixation part, so that the position of the guide part relative to the fixation part can be adjusted in at least two degrees of freedom. It will often be particularly preferred for the guide block to include at least three drives so that the position of the guide part relative to the fixation part can be adjusted in three or more degrees of freedom, for example four or five degrees of freedom.

The guide block can include an electric motor for causing relative rotation between the shaft and the bore. The motor can be provided within the guide block, for example in the fixation part. Alternatively, the motor can be outside the guide block. Drive from the motor to the guide block can be provided by means of a suitable drive shaft connector.

Preferably, the guide block includes at least one position indicator which is fixed relative to the guide part, and at least one position monitor for tracking the location of the position indicator, so that the position of the guide part relative to a reference point can be determined. The guide block will preferably include three (or more) position indicators so that the location and orientation of the guide part can be determined accurately. Position indicators which can be used in surgical procedures are known. Suitable position indicators include passive indicators which are reflective and emitting indicators such as those which comprise one or more light emitting diodes. A guide block with one or more position indicators can be used in a system which includes a position detector which can detect signals from the position indicator, and determine the location and/or orientation of the guide part relative to a reference coordinate system. Preferably, the system will include position detectors which provide signals to allow the location and/or orientation of the patient to be determined as well.

The guide block can be provided as part of a drive system for use in surgery, which also includes a signal generator which is connected to the drive, for generating position signals

which are transmitted to the drive to cause the guide part to move relative to the fixation part.

The guide block of the invention finds particular in orthopaedic surgery where accurate positioning of instruments used in surgery, and of prosthesis components, is vitally important. For example, the guide block of the invention can be used to locate a saw relative to anatomical features, especially on a bone, for a resection step. For example, it can be used to locate the plane for the resection of the tibia in the implantation of a knee joint prosthesis. In this procedure, a guide block will have a surface against which a saw blade can be positioned, especially a pair of surfaces which define a slot. The guide block is fastened to the tibia in approximately the correct location relative to previously identified anatomical landmarks, for example by three bone screws which pass through fixation holes in the fixation part of the block. The guide block will include three drives by which the location of the guide part can be adjusted relative to the fixation part. A first drive can adjust the anterior-posterior tilt of the guide part. The second drive can adjust the medial-lateral tilt of the guide part. The third drive can adjust the spacing between the guide and fixation parts along a desired axis, for example essentially along the patient's anatomical axis.

The guide block of the invention will preferably be made from a metallic material, such as used conventionally for surgical instruments. Examples of suitable materials include certain stainless steels.

Embodiments of the present invention will now be described by way of example with reference to the accompanying drawings in which:

Figure 1 is an isometric view showing a guide block according to the present invention, which can be used to locate the tibial resection plane in a surgical procedure to implant a knee joint prosthesis.

Figure 2 is an isometric view of another embodiment of guide block according to the present invention.

Referring to the drawings, Figure 1 shows a guide block 2 which comprises a fixation part 4 and a guide part 6. The fixation part 4 has three holes 8 extending through it by which it can be fixed to a patient's tibia by means of bone screws. The location for fixing the fixation part of the guide block to the tibia can be determined with reference to anatomical landmarks which are identified in pre-operative planning stages of the surgical procedure.

The guide part 6 of the fixation block has a slot 10 in it. The slot extends through the guide part so that a blade inserted into the slot can extend through it and be used to cut a bone to which the guide block is fixed. The slot will be dimensioned so that the blade is a sliding fit, as in existing cutting blocks.

The location and orientation of the resection plane is determined by the position of the slot 10 relative to the patient's bone. This can be adjusted by movement of the guide part 6 of the cutting block relative to the fixation part 4.

The fixation part has three control knobs on it. Each of them forms part of a drive which can be used to adjust the location and orientation of the guide part relative to the fixation part. A first knob 12 is used to adjust the anterior-posterior tilt of the guide part. A second knob 14 is used to adjust the medial-lateral tilt of the guide part. A third knob 16 is used to adjust the spacing between the guide and fixation parts, essentially along the patient's anatomical axis.

Remote operation of the drives can be achieved using flexible drive shafts which are connected to the guide part of the guide block. For example, a drive shaft having a hexagonal male part can be received in a hexagonal socket on the fixation part of the guide block. The drive shaft can be operated manually, remotely of the guide block. Alternatively, the drive shaft can be driven remotely by a motor.

Figure 2 shows a guide block which is similar to that shown in Figure 1. However, instead of having knobs 12, 14, 16 to control the movement of the fixation part 4 relative to the

guide part 6, the block includes three motors 22, 24, 26. Signals are supplied to the motors from a signal generator to cause them to move the guide part of the guide block.

The guide part additionally includes three position indicators 30. Each of the position indicators can comprise an array of light emitting diodes as known for use in navigation systems used in surgical procedures. Other position indicators are known.

The guide block shown in Figure 2 is used as part of a computer assisted surgical navigation system including position indicators (not shown) which can be fixed to the patient's bone to allow information to be generated about the location and orientation of the bone. The system further includes a position detector 32 which can detect signals from the position indicators. Data that is derived from the position indicators using the position detector can be used to generate information as to the positions of the bone and the guide part, using a computer 34. The computer also includes a signal generator 36 by which drive signals for the motors 22, 24, 26 can be generated. If it is determined that the guide part is not located or oriented appropriately relative to the bone, its location and/or orientation can be adjusted by providing signals to the motors 22, 24, 26 by means of the signal generator.

CLAIMS:

1. A guide block for use in surgery to locate a surgical tool accurately relative to an anatomical feature, which comprises a fixation part which can be fastened directly to the patient's tissue, and a guide part having at least one structural feature to engage a surgical tool to ensure that the tool is located appropriately relative to the patient's tissue, the guide part being mounted on the fixation part, the instrument including at least one indexed drive by which the position of the fixation part relative to the guide part can be adjusted.

2. A guide block as claimed in claim 1, in which the structural feature comprises a guide surface which can be engaged by a blade to define the appropriate alignment for a cut.

3. A guide block as claimed in claim 1, in which the structural feature comprises an opening in which a drill bit can be inserted.

4. A guide block as claimed in claim 1, in which the fixation part has at least one opening extending through it in which a fastener can be located for fixing the part to the patient's tissue.

5. A guide block as claimed in claim 4, in which the fixation part has a plurality of openings extending through it in which fasteners can be located for fixing the part to the patient's tissue.

6. A guide block as claimed in claim 1, in which the drive includes at least one threaded shaft on one of the fixation part and the guide part, and a threaded bore in the other of the fixation part and the guide part in which the threaded shaft can be received, in which the position of the guide part relative to the fixation part can be adjusted by rotating the shaft relative to the bore.

7. A guide block as claimed in claim 6, in which the drive includes a knob which can be engaged manually to cause relative rotation between the shaft and the bore.

8. A guide block as claimed in claim 6, which includes an electric motor for causing relative rotation between the shaft and the bore.

9. A guide block as claimed in claim 6, which includes a flexible drive shaft which can be connected to the guide part, through which rotational motion can be imparted to the guide part from a remote location to cause relative rotation between the shaft and the bore.

10. A guide block as claimed in claim 1, which includes at least two drives for adjusting the position of the guide part relative to the fixation part, so that the position of the guide part relative to the fixation part can be adjusted in at least two degrees of freedom.

11. A guide block as claimed in claim 1, which includes at least one position indicator which is fixed relative to the guide part, and at least one position monitor for tracking the location of the position indicator, so that the position of the guide part relative to a reference point can be determined.

12. A drive system for use in surgery, which includes guide block as claimed in claim 11, and a signal generator which is connected to the drive, for generating position signals which are transmitted to the drive to cause the guide part to move relative to the fixation part.

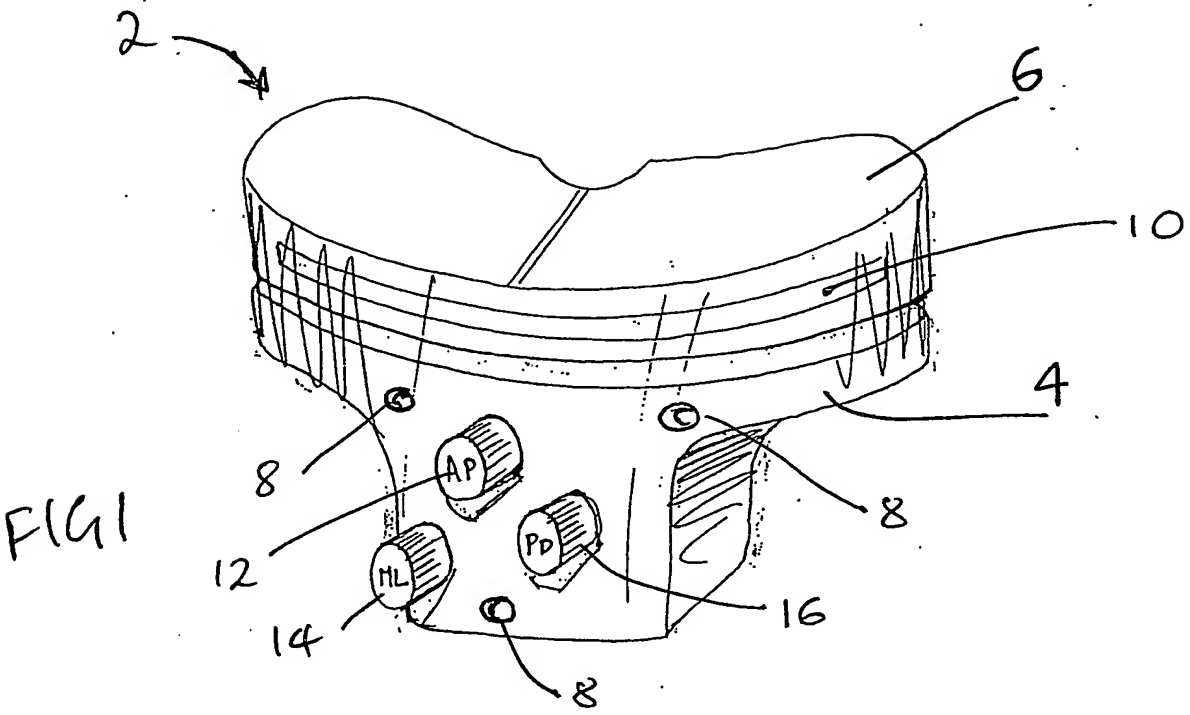

FIG1

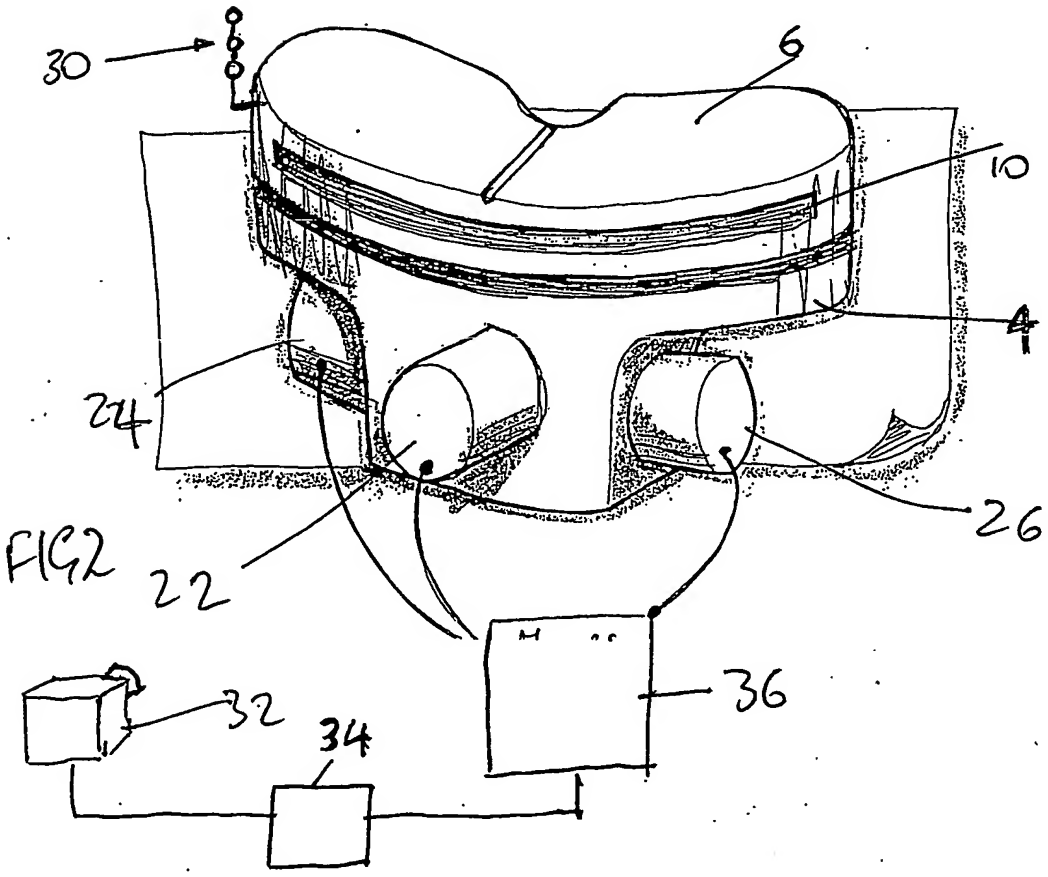

FIG2